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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,220	11/27/2000	Wolfgang Fleischer	228.1006	8087

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/701,220	Applicant(s) FLEISCHER ET AL.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment dated 2-26-06 is acknowledged.

Claims included in the prosecution are 54-78.

Double Patenting

1. The obviousness type double patenting of claims (now 54-78) over claims of 09/701,450 as set forth in the previous action is maintained in abeyance.
2. In view of the amendment to the claims, the 112 rejections and the 102 rejection of claims over Knight are withdrawn.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 54-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0639 373 in view of Knight (5,049,388) as set forth in the previous action.

Applicant's arguments have been fully considered, but are not found to be persuasive. Based on the declaration (paragraph 5), applicant argues that the aim of wound treatment is generally to keep the number of microorganisms in the wound as low as possible in order to prevent the infection and sepsis, and at the same time, to stimulate the repair process in order to achieve optimum healing and quality of wound closure, including restoring the tissue at the wound site to its original appearance and function and that the agents that stimulate healing, which are largely based on maintaining moisture content, are usually contraindicated in the presence of a potential infection since moist treatment of wounds increases the risk of bacterial infection.

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According to Dr. Fleischer's declaration, antiseptics and antibiotics are mostly inhibitory to granulation or epithelialization. Applicant argues that 373 patent (EP) teaches the administration of liposomes containing povidone iodine externally to the skin or eye for the treatment of invention and that EP teaches additional wound healing promoting agent. These arguments are not persuasive since the prior art of EP recognizes that povidone iodine is specifically applicable to epithelial cells (page 2, lines 1-3).

Furthermore, according to instant specification, additional wound healing agents can be added just as in EP. Instant claim 59 recites allantoin, vitamin B and azulenes which applicant argues that the compositions in EP contain. Thus, applicant argues that there is no disclosure in 373 that teaches or suggests that liposomes containing povidone iodine can be used without a wound healing promoting agent for promoting the healing of the wounds.

Applicant argues that there is no teaching or suggestion in the 373 patent that the liposomes containing povidone iodine could be administered to any other part of the body other than to external parts of the body such as the skin and the mucous membrane of the eye. This argument has been addressed before many times. In essence, although the composition in EP is for external use, EP clearly teaches on page 2, lines 1-9 that the preparations are meant for application to the mucous membranes in humans and furthermore, EP is directed to the treatment of eye conditions. This is suggestive of the safe application of the compositions even for nasal or oral or tracheal mucous tissues. Furthermore, EP at the same location teaches that different antibiotics and antiseptic agents are known for the topical treatment of infectious diseases and that

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while antibiotics quite often lead to patient sensibilization, antiseptic agents such as PVP-iodine can prevent resistances and that they are much more rarely allergenic, as compared to antibiotics. The safe nature and the effectiveness of the liposomes and the safe nature of the anti-microbial povidone iodine is obvious from the combined teachings of the references and hence one of ordinary skill in the art would be motivated to use the compositions containing PVP-iodine of EP by inhalation route taught by Knight. Contrary to applicant's arguments, the examiner has provided clear and particular showing there is motivation to combine the references. Furthermore, the examiner points out that applicant himself have not demonstrated the safety and effectiveness of the composition when administered internally. Instant specification contains only in vitro data, that too against a single organism. According to applicant, PVP-iodine alone would be highly detrimental to ciliated lung cells in vivo whereas application of liposome containing PVP-iodine would not harm the ciliated lung cells. These arguments are not found to be persuasive since that is the point the examiner raised; that is, these results are from in vitro studies and there is no in vivo data to show that this compound is safe when administered internally. It is interesting to note that in previously presented claims, Applicant argues that Knight does not fill in the gap between the claimed invention and the disclosure of the 373 patent. According to applicant, Knight discloses small aqueous aerosol droplets containing liposomes and wherein such liposomes are interacted with drugs and their use in treating medical conditions in the lungs. Also according to applicant, Knight does not teach or suggest that such liposomes can be used for suppressing undesired tissue formation or for

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restoring the original appearance of tissue at a site of tissue damage in the respiratory tract. These arguments are not persuasive since Knight's formulations are intended for the delivery through the respiratory tract and the administered compounds would therefore be available throughout the respiratory tract. Furthermore, instant claims recite two functions: one suppressing undesired tissue formation or for restoring the original appearance. Since once the infection is treated, the tissue returns to the original condition, which also suppresses the scar formation, the combination of references, meet the requirements of instant claims.

5. Claims 54-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP (0639373) in combination with either knight (5,049,388) as set forth above, in further combination with WO 85/00112.

The teachings of EP and Knight have been discussed above.

WO teaches the administration of vaporized microbicidal agent such as povidone-iodine for the treatment of the symptoms of a viral or bacterial infection. The administration is by nasal route (abstract and claims, claims 1 and 7 in particular).

One of ordinary skill in the art would be motivated further to administer the liposomal compositions containing povidone-iodine taught by EP to restore the original appearance of upper respiratory tract after an infection, since the reference of WO shows that povidone-iodine can be administered safely by inhalation route to treat viral and bacterial infections.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK